

Decision Memo for Hepatitis Panel/Acute Hepatitis Panel (Addition of ICD-9-CM 790.4, Elevation of Levels of Transaminase or Lactic Acid Dehydrogenase) (CAG-00304N)

Decision Summary

CMS has determined that ICD-9-CM diagnosis code 790.4, Nonspecific elevation of levels of transaminase or lactic acid dehydrogenase, flows from the existing narrative for conditions for which a Hepatitis Panel/Acute Hepatitis Panel of tests is reasonable and necessary. We shall modify the list of "ICD-9-CM Codes Covered by Medicare Program" in the NCD for Hepatitis Panel/Acute Hepatitis Panel by adding code 790.4.

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Decision Memo

This coding analysis does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue a change to the list of ICD-9-CM Codes Covered that are linked to one of the negotiated laboratory NCDs. This decision will be announced in an upcoming recurring update notification in accordance with CMS Pub 100-4, Chapter 16, Section 120.2 and will become effective as of the date listed in the transmittal that announces the revision.

TO: Administrative File: CAG – 00304N Addition of ICD-9-CM 790.4, Nonspecific Elevation of Levels of Transaminase or Lactic Acid Dehydrogenase

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SUBJECT: Addition of ICD-9-CM 790.4, Nonspecific Elevation of Levels of Transaminase or Lactic Acid Dehydrogenase, as a Covered Indication for the Hepatitis Panel/Acute Hepatitis Panel National Coverage Determination (NCD).

DATE: December 14, 2005

I. Decision

CMS has determined that ICD-9-CM diagnosis code 790.4, Nonspecific elevation of levels of transaminase or lactic acid dehydrogenase, flows from the existing narrative for conditions for which a Hepatitis Panel/Acute Hepatitis Panel of tests is reasonable and necessary. We shall modify the list of "ICD-9-CM Codes Covered by Medicare Program" in the NCD for Hepatitis Panel/Acute Hepatitis Panel by adding code 790.4.

II. Background

On October 24, 2005, CMS formally accepted a request for consideration to add ICD-9-CM code 790.4 to the covered indication code list for the Hepatitis Panel/Acute Hepatitis Panel NCD. The transaminases (alanine aminotransferase (ALT) and aspartate aminotransferase (AST)) and lactic dehydrogenase (LDH) are intracellular enzymes that can be elevated in association with damage to the liver and other organs. Often, viral hepatitis infection is detected when there are abnormal liver test results, with or without signs or symptoms of hepatitis.

III. History of Medicare Coverage

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that specific tests were reasonable and necessary for certain medical indications. These decisions were evidence-based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled "ICD-9-CM Codes Covered by Medicare," and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled "ICD-9-CM Codes Denied," and lists diagnosis codes that are never covered by Medicare. The third list is entitled "ICD-9-CM Codes That Do Not Support Medical Necessity," and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary.

IV. Timeline of Recent Activities

On October 24, 2005, CMS opened a coding analysis item regarding the addition of ICD-9-CM 790.4, Nonspecific elevation of levels of transaminase or lactic acid dehydrogenase, as a covered indication for the Hepatitis Panel/Acute Hepatitis Panel National Coverage Determination (NCD). We posted a tracking sheet to the Internet (<http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=173>) and solicited public comment for 30 days on the appropriateness of adding code 790.4 to the list of covered codes for the Hepatitis Panel/Acute Hepatitis Panel NCD.

We received eight comments during the comment period, which ended November 24, 2005. One commenter felt that elevations of liver enzymes are quite prevalent and usually transient. The individual felt that adding the code may add costs but render low yield. The remaining comments supported the addition of 790.4 to the list. One respondent stated that it would be helpful if we differentiated between acute hepatitis panel and chronic hepatitis panel. The person noted that patients who have a mildly elevated transaminase may receive a false positive Hepatitis A IgM resulting in unnecessary and burdensome follow up procedures.

The majority of respondents agreed that the indication flowed from the narrative of the NCD. In addition, several respondents noted that ordering a hepatitis panel for any liver test elevation is standard practice for many physicians.

V. General Methodological Principles

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. Thus, all of the codes in the covered code list must flow from the narrative indications of the NCD. We reiterated this position in the November 23, 2001 final rule (66 FR 58795) and in subsequent implementing instructions (Program Memorandum AB-02-110).

On February 25, 2005, we announced in a final notice in the Federal Register (70 FR 9355) that we would maintain the accuracy of the coding lists without substantive changes to the narrative policy through an abbreviated process that did not require scientific evidence. We call this abbreviated process the Coding Analysis for Laboratories (CAL).

VI. CMS Analysis

The "ICD-9-CM Codes Covered by Medicare" list is intended to contain only those codes that flow from the narrative of the indication in the NCD. The Hepatitis Panel/Acute Hepatitis Panel NCD narrative includes the following indication:

"This panel of tests is used for differential diagnosis in a patient with symptoms of liver disease or injury."

We believe that the ICD-9-CM code 790.4, Nonspecific elevation of levels of transaminase or lactic acid dehydrogenase, flows from the narrative indication statement quoted above as these tests are indicators of liver damage.

Hepatitis is an inflammation of the liver resulting from viruses, drugs, toxins, and other etiologies. Viral hepatitis can be due to one of at least five different viruses, designated Hepatitis A, B, C, D, and E. Most cases are caused by Hepatitis A virus (HAV), Hepatitis B virus (HBV), or Hepatitis C virus (HCV). Characteristically, viral hepatitis causes high elevations of the levels of transaminases and LDH.

In response to the public commenters, we believe that a thoughtful clinician should order and interpret hepatitis testing in light of the patient's history and clinical presentation to avoid subjecting the patient to unnecessary and burdensome follow up procedures. For an individual patient, the physician can separately order those components that are appropriate, based on the clinical presentation. In addition, there are other available hepatitis tests that are not included in the NCD, but that may be appropriate clinically.

We intend to issue a recurring update to the edit module implementing the NCDs to add ICD-9-CM code 790.4 to the list of the ICD-9-CM codes covered for the Hepatitis Panel/Acute Hepatitis Panel of tests.

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